K012724

Endoscopy Division

Smith & Nephew, Inc.
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Smith+Nephew

NOV 0 8 2001

510(k) Summary
Smith & Nephew Vascular VideoEndoscope
Date Prepared:

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, MA 01810

B. Company Contact

Janice Haselton
Regulatory Affairs Specialist

C. Device Name

Trade Name: Smith & Nephew Vascular VideoEndoscope
Common Name: Vascular Endoscope
Classification Name: Endoscope and/or Accessories

D. Predicate Devices

Olympus Endoscopic System for Vessel Harvesting K963184
Ethicon's EndoPath Ultra Retractor and Vessel Dissector K973139
Smith & Nephew's Images Endoscopes K971850

E. Description of Device

The proposed Smith & Nephew Vascular VideoEndoscope is designed in an "L" shaped configuration as to have the horizontal optical train and working channel as the part that is introduced into the leg and the vertical shaft as a handle. The connecting cables and tubing are conveniently located far from the leg to minimize any interference with the surgeon's hand movements. The function of the Smith & Nephew

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Vascular VideoEndoscope is to create and maintain a subfascially working space, provide visualization of the working space, and provide access to hand instruments to the working space.

The attachments utilize the same locking feature located on the endoscope which allows the Smith & Nephew Vascular VideoEndoscope to be used as a multi-purpose device.

F. Intended Use

The Smith & Nephew Vascular VideoEndoscope is indicated for use in subcutanous endoscopy, specifically for endocopically gaining access to, ligating and/or harvesting vessels within the subcutaneous and subfascial surgical planes in the lower extremities.

G. Comparison of Technological Characteristics

The Smith & Nephew Vascular VideoEndoscope is substantially equivalent in design, materials of construction and function and intended use as to the Olympus Endoscopic System for Vessel Harvesting, Smith & Nephew's Images Endoscopes, and Ethicon's EndoPath Ultra Retractor and Vessel Dissector.

Janice Haselton

Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 8 2001

Ms. Janice Haselton
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, Massachusetts 01810

Re: K012724
Trade/Device Name: Smith & Nephew Vascular VideoEndoscope
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: KOG
Dated: August 14, 2001
Received: August 14, 2001

Dear Ms. Haselton :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walk, for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number : K012724

Device Name : Smith & Nephew Vascular VideoEndoscope

Indications for Use :

The Smith & Nephew Vascular VideoEndoscope is indicated for use in subcutanous endoscopy, specifically for endocopically gaining access to, ligating and/or harvesting vessels within the subcutaneous and subfascial surgical planes in the lower extremities.

(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter ____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Susan Walk
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012724